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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,921	08/27/2001	Mark L. Chivers	11916.0042.DVUS01	5294

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EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/939,921	Chivers
Examiner	**Art Unit**
Michael Borin	1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) [X] Responsive to communication(s) filed on *May 6, 2003* .

2a) [ ] This action is **FINAL**. 2b) [X] This action is non-final.

3) [ ] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) [X] Claim(s) *36-52* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) [ ] Claim(s) _____ is/are allowed.

6) [X] Claim(s) *36-52* is/are rejected.

7) [ ] Claim(s) _____ is/are objected to.

8) [ ] Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) [ ] The specification is objected to by the Examiner.

10) [ ] The drawing(s) filed on _____ is/are a) [ ] accepted or b) [ ] objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) [ ] The proposed drawing correction filed on _____ is: a) [ ] approved b) [ ] disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) [ ] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) [ ] Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) [ ] All b) [ ] Some* c) [ ] None of:

1. [ ] Certified copies of the priority documents have been received.
2. [ ] Certified copies of the priority documents have been received in Application No. _____ .
3. [ ] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) [ ] The translation of the foreign language provisional application has been received.

15) [ ] Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) [X] Notice of References Cited (PTO-892)
2) [ ] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [ ] Information Disclosure Statement(s) (PTO-1449) Paper No(s).
4) [ ] Interview Summary (PTO-413) Paper No(s).
5) [ ] Notice of Informal Patent Application (PTO-152)
6) [ ] Other:

DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 05/06/2003 is acknowledged. Examiner acknowledges that in view of earlier unaccounted for preliminary amendment canceling claims 1-35, the restriction requirement is moot. Accordingly, claims 36-52 are being examined.

Drawings

2. The drawings are approved.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 40-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. The specification does not provide support for use of polysaccharides having polymer charge density of <30%. Charge density range is addressed ion page 9, and in Table 1 in regard to polyacrylamides rather than to polysaccharides.

4. Claim 43 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the concentration range of 20-30 ppm as claimed.

5. Claims 49, 51,52 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not provide support for the combination of specific ranges of parameters as claimed.

6. Claims 36,40-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polyacrylamide and potato starch, does not reasonably provide enablement for other polymers, in particular, other polysaccharides. The working examples and guidance in the specification are focused on use of polyacrylamide; also use of potato starch is addressed in example 6. In regard to polysaccharides neither polysaccharides other than potato starch are described, nor their charge density and selection are addressed. The specification does not enable use of any other anionic polymers and an artisan is not enabled to use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 102 and 103.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the

examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 36,40-48,50 are rejected under 35 U.S.C.103(a) as obvious over Oechslein et al (International Journal of Pharmaceutics (1996), 139(1,2), 25-32)

Oechslein et al. teaches formulations comprising somatostatin analog ostreotide and absorption modifier, such as starch. See abstract. As such, the components of the referenced composition read on instantly claimed composition comprising somatostatin and anionic polymer, such as starch. In regard to "aqueous suspension" limitation, the referenced powdered composition turns into aqueous suspension at least in the course of drug release studies (section 2.4) or water uptake studies (p.28, section 3.2); furthermore, as the referenced composition is intended to be used for pharmaceutical delivery, its content will obviously become an aqueous suspension under physiological conditions.

In regard to the presence of somatostatin analogs (as in claim 36) or particular somatostatin (as in claim 50), selection of functionally equivalent somatostatin analogs would be obvious to one skilled in the art.

In regard to the limitations of molecular weight and amount of the excipient, the reference is silent about particular ranges of these parameters, but their selection would be obvious to one skilled in the art as a part of routine optimization.

In regard to the limitation of "charge density", the reference does not address the starch excipient in such terms, and since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

8. Claims 36,40,41,43-48,50 are rejected under 35 U.S.C.103(a) as obvious over Takama et al (US 5,929,027).

Takama teaches sublingual tablets comprising physiologically active peptides, such as, e.g., somatostatin (see col. 3, line 19), and excipients, such as starches or modified celluloses (carboxymethylcellulose, hydroxypropyl cellulose, etc - see col. 4, lines 22-33). In regard to "aqueous suspension" limitation of the instant claims, as the referenced tableted composition is intended to be used for pharmaceutical delivery, its content will obviously become an aqueous suspension under physiological conditions.

In regard to the limitations of molecular weight and amount of the excipient, the reference is silent about particular ranges of these parameters, but their selection would be obvious to one skilled in the art as a part of routine optimization.

In regard to the presence of somatostatin analogs (as in claim 36) or particular somatostatin (as in claim 50), selection of functionally equivalent somatostatin analogs would be obvious to one skilled in the art.

In regard to the limitation of "charge density", the reference does not address the starch excipient in such terms, and since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

9. Claims 36-39,43-48,50 are rejected under 35 U.S.C.103(a) as obvious over Churchill et al. (US 4,942,035).

Churchill teaches aqueous suspensions of physiologically active peptides, such as, e.g., somatostatin (see col. 3, line 1), and hydrophilic polymer B, such as polyacrylamide (see col. 4, line 25), the latter might be copolymerized with another hydrophobic polymer (see col. 3, lines 25-31). The polymer used in the composition is of molecular weight of >5000.

In regard to the presence of somatostatin analogs (as in claim 36) or particular somatostatin (as in claim 50), selection of functionally equivalent somatostatin analogs would be obvious to one skilled in the art.

In regard to the limitation of "charge density", the reference does not address the starch excipient in such terms, and since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

In regard to the limitations of particular molecular weight and amount of the excipient, the reference is silent about particular ranges of these parameters, but their selection would be obvious to one skilled in the art as a part of routine optimization.

10. Claims 36,40-45,50 are rejected under 35 U.S.C.103(a) as obvious over Holmberg et al. (WO 98/28336).

The reference teaches compositions comprising conjugates of somatostatins and charged polysaccharides. As the composition instantly claimed is described using open language "comprising" without specifying whether the components are present separately or are connected, the referenced composition is considered as reading on the claimed composition. Somatostatins can be any somatostatin analog (see p. 7,

top). The molecular weight of the charged polysaccharide is 10,000-150,000 (p. 5) and the effective charge is about 10 charged units (p. 5).

In regard to the limitation of "charge density", the reference teaches how to determine the "effective surface charge" (see pages 5,21), but does not express it in the same units as in the instant claims. Since the Office does not have the facilities for examining and comparing applicants' composition with the composition of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art.

In regard to claims 41,42, selection of particular charged polysaccharides would be obvious to one skilled in the art as a part of routine optimization.

In regard to claims 43-45, the amount of polysaccharides in this instance will correspond to the amount of conjugate, and selection of the effective concentration of the latter for a particular application (see claims 27,28) will be obvious to one skilled in the art as a part of routine optimization.

Conclusion.

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703)

305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

July 14, 2003

mlb